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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	59046.000044	7675

21967 7590 11/04/2008

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
11/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,488	ILAN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52 and 55-62* is/are pending in the application.

4a) Of the above claim(s) *61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52, 55-60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-49 and 53-54 are cancelled. Claims 50-52 and 55-62 are pending. Claim 61 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/02/2005. Claims 50-52, 55-60 and 62 are under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 50-52 and 55-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuji et al.[1]

In response to the rejection, Applicant argues that Tsuji et al. does not teach every element of the claimed invention for the composition taught and disclosed by Tsuji et al. is not a mammalian metabolite. Applicant also argues unexpected results.

Applicant's argument has been considered, however, it is not found persuasive. Applicant discloses that the mammalian metabolite is a glycolipid, wherein the glycolipid is a monosaccharide, which is later disclosed as galactosylceramide and

glucosylceramide. See claim 56. And Tsuji et al. teaches both galactosylceramide and glucosylceramide. Thus, contrary to Applicant's assertion, the composition of Tsuji et al. is the same as those recited in the claims. It should be noted that a known composition is not patentable upon discovery of an unappreciated property or the use of different trade name. MPEP 2112. That is, Tsuji et al. does not need to appreciate that galactosylceramide and glucosylceramide as metabolites in order to render the claimed invention obvious. Tsuji et al. teaches that galactosylceramide and glucosylceramide have adjuvant activity and teaches the administration of galactosylceramide and glucosylceramide to modulate the immune response in a subject. Tsuji et al. teaches the same method as those instant claimed. Therefore, the method of Tsuji et al. anticipates the claimed invention.

Applicant's argument of unexpected results has been noted, however, it is not persuasive. The rejection is an anticipatory rejection not an obviousness rejection. Anticipatory rejection cannot be obviated with unexpected results. The claims remain rejected for the reason(s) set forth in the record.

The claims are directed to a method of modulating an immune response in a mammal with the administration of a glycolipid. Claim 51, which depends on claim 50, requires that the humoral, cellular or cytokine component of the immune system be modulated. Claim 52, which depends on claim 50, requires the modulation be specific or non specific. Claim 55, which depends on claim 50, limits the glycolipid to a monosaccharide ceramide. Claim 56, which depends on claim 55, limits the monosaccharide to glucosylceramide or galactosylceramide. Claim 57, which depends

[1] Tsuji et al. U.S. PreGrant Patent Publication No. 20030157135, filed July 25, 2002.

on claim 50, requires the administration method be intravenous, intra-muscular, subcutaneous, intra-peritoneal or oral.

Tsuji et al. teaches the administration of galactosylceramide to modulate the immune response in a mammal. [Entire PreGrant Patent Publication, claim 12, in particular.] Specifically, Tsuji et al. teaches that galactosylceramide is immunostimulatory, including the induction of a Th1 biased, cellular, including the production of cytokines, immune response. [Paragraph [0190], in particular.] The administration method used by Tsuji et al. includes intravenous, subcutaneous and intra-peritoneal. Tsuji et al. teaches the claimed composition. Hence, Tsuji et al. anticipates the claimed invention.

Regarding claims 58-60, which requires the immune response being modulated is part of the pathogenesis of an infection, including HCV, it should be noted that the because of the immunostimulatory nature of galactosylceramide, the administration of galactosylceramide would necessarily modulate the immune response in an individual, regardless of the type of disease the individual is diagnosed. Furthermore, Tsuji et al. also notes the administration of galactosylceramide to modulate the immune response that is part of HIV infection. [See claim 20, in particular.]

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 50 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al., as applied to claim 50.

In response to the rejection, Applicant argues that Tsuji et al. does not render the claimed invention obvious because there is no motivation to alter the reference and no reasonable expectation of success

Applicant's argument has been considered, however, it is not found persuasive. Tsuji et al. clearly teaches that galactosylceramide and glucosylceramide have adjuvant activities. Tsuji et al. also clearly teaches the use of galactosylceramide and glucosylceramide as adjuvants in vaccines. Moreover, Tsuji et al. clearly suggests administration to a human. Thus, contrary to Applicant's assertion, Tsuji et al. provides plenty of motivation.

It is noted that in supporting the lack of motivation argument, Applicant argues that Tsuji et al. does not render the claimed invention obvious because Tsuji et al. suggests the administration of galactosylceramide and glucosylceramide with an antigen in a vaccine; whereas, the claimed invention is not directed to the administration of the antigen. Applicant also uses this argument to support Applicant's assertion that Tsuji et al. teaches away from the claimed invention. However, it should further be noted that the claims recite the transitional term "comprising". This transitional term allows for the administration of antigens, along with glycolipids such as galactosylceramide and glucosylceramide. Moreover, this specific teaching of Tsuji et al. is not a "teaching away", as alleged by Applicant. Therefore, Applicant's arguments have been considered, however, none are found persuasive.

Regarding Applicant's argument of no reasonable expectation of success, it should be noted that the requirement is "reasonable expectation of success" not "absolute expectation of success". As noted above, Tsuji et al. teaches that galactosylceramide and glucosylceramide have adjuvant activities. Tsuji et al. teaches that galactosylceramide and glucosylceramide can be used as adjuvants in vaccines. In the instant case, Tsuji et al. has established a prima facie case that galactosylceramide and glucosylceramide are adjuvants. Thus, it is expected that when galactosylceramide and glucosylceramide would modulate the immune response to an antigen when they are administered to a human. In the instant case, neither Tsuji et al. nor Applicant has provided any evidence that would doubt the reasonable expectation of success.

Claim 62, which depends on claim 50, limits the mammal to a human. Tsuji et al. did not administer galactosylceramide to a human. However, Tsuji et al. does suggest such administration to a human.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer galactosylceramide to a human. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate the immune response in the human. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the immunostimulatory activity of galactosylceramide is known in the art.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 50-52, 55-60 and 62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 9 and 11 of copending Application No. 10/375906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of

both applications are directed at a process comprising the administration of a glycolipid to a virally infected subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./